Approval: Original Signed by Mark Arenaz Date: 02/14/03
Manager, National Spent Nuclear Fuel Program

Approval: Original Signed by Robert Blyth Date: 02/14/03
NSNFP Quality Assurance Program Manager

I. PURPOSE AND SCOPE

This procedure establishes the process and responsibilities of the National Spent Nuclear Fuel Program (NSNFP) for conducting quality assurance (QA) audits of NSNFP, NSNFP suppliers, spent nuclear fuel sites, and other activities requested by the NSNFP Quality Assurance Program Manager (QAPM).

II. SUMMARY

This procedure covers audit team selection, audit notification, planning, preparation, performance, and reporting for internal and external audits.

III. PROCEDURE

A. Audit Team Selection

QAPM/QASM

1. Select audit team members during assessment planning and scheduling activities (QAS 18.01, "Planning and Scheduling Assessments").

2. Ensure that selected audit team members:

   a. Have sufficient authority and organizational freedom to make the audit process meaningful and effective.

   b. Are independent of any direct responsibility for performing the work being audited.

   c. Collectively have experience and/or training commensurate with the scope, complexity, or special nature of the activities to be audited.

3. Assign an audit team lead (ATL) to manage the audit.

   a. Prior to commencing the audit process, verify by completing NSNFP Form 18.04-6 that the ATL meets the requirements of QAS 18.04.

ATL

4. Prior to commencing the audit, verify by completing NSNFP Form 18.04-6 that auditors and technical specialists meet the training requirements specified in NSNFP procedure QAS 18.04.

QAPM/QASM

5. Provide the resources necessary for the audit team to implement the audit.

B. Audit Notification

ATL

1. Contact responsible management of the program or organization to be audited to determine the audit scope, identify distribution for the letter, and confirm the audited organizations availability and activity schedules. If necessary to accomplish these tasks, arrange to meet with the organization to be audited.

2. Prepare an announcement letter for the organization being audited. This announcement letter needs to:

   a. Inform them of the scheduled audit.

   b. Describe the scope of the audit. Base the audit scope on: implementing documents, current work activities, results of previous assessments (including follow-up on previously identified deficiencies), impact of significant changes in personnel and organizations, and any programmatic issues, (e.g., significant organizational changes or QA program changes).

   c. List scheduled dates of the audit, including pre- and post-audit meeting dates, times, and locations, if known.

   d. Request that points of contact are established for introduction at the preaudit conference.

   e. Request access to related facilities, documentation, and personnel.

   f. Request that facilities be made available for the audit team to conduct daily activities and team meetings.

QASM/QAS

3. Sign the notification letter and distribute it 30 calendar (guideline) days prior to the preaudit conference.

C. Audit Planning and Preparation

ATL

1. Prepare an audit plan using the format and content of the example in Attachment A.

2. Verify that audit team members collectively have the experience or training commensurate with the scope, complexity, and special nature of the work to be audited.

3. Signify that audit team members meet all the requirements by signing the audit plan and forward to the QAPM.

QAPM

4. Review and approve the audit plan for completeness and compliance to this procedure.

ATL

5. Meet with the audit team and audit observers prior to the preaudit conference, individually or as a group, to review the audit plan and expectations of team members. Use this meeting to:

   a. Give each auditor a copy of the audit plan and familiarize them with its contents.

   b. Make activity assignments based on each auditor's or technical specialist's expertise.

   c. Provide the schedule for completing and approving checklists, and provide audit checklist macros to team members who do not have access to the NSNFP forms, or use previously generated checklists approved by the ATL.

   d. Review requirements for documenting deficiency reports (DRs) and conditions adverse to quality that are corrected during the audit (CDA).

   e. Review documentation and report content required from each team member.

   f. Provide all observers with copies of Form 18.02-1/18.03-1 "Observer Inquiry," for use during the audit, and ensure users know how to use it.

   g. Ensure the audit team is prepared before the preaudit conference.

Audit Team

6. Prepare the audit checklist in accordance with Form 18.02-3/18.03-3, "NSNFP Audit/Surveillance Checklist," or a similar format. Provide the checklist to the ATL for approval.

Technical Specialists

   a. List the standards, specifications, and critical steps of the engineering analysis, scientific investigation, or processes being evaluated on a checklist, and submit it to the ATL for approval.

ATL

7. Approve the Audit Checklist (Form 18.02-3/18.03-3, or similar form) with printed name, signature, and date.

Audit Team

8. Prepare for the audit by studying the final audit plan, checklist, and any other program and technical documents considered appropriate.

D. Audit Performance

ATL

1. Conduct a preaudit conference with the management of the organization being audited to:

   a. Introduce the audit team and observers.

   b. Outline the scope, schedule, and objective of the audit.

ATL

c. Outline the activities to be covered by each team member.

d. Identify the escorts (if required).

e. Identify the subject matter points of contact.

f. Establish the necessary channels of communication for reporting concerns and conditions adverse to quality.

g. Review the process for resolving conditions adverse to quality, including conditions corrected during the audit.

2. Conduct regularly scheduled briefing meetings with the audit team to discuss audit progress and identified issues.

3. Conduct regularly scheduled briefing meetings with management of the audited organization to discuss audit progress and identified issues.

4. The ATL is responsible for:

a. Managing the audit

b. Supervising the audit team

c. Coordinating the preparation and issuance of DRs

d. Evaluating the significance of DRs

e. Identifying the corrective action requests (CARs)

f. Evaluating the stop work orders

g. Generating the audit report

h. Accumulating the records.

Audit Team

5. Use the approved checklist as a guide to determine compliance, observe work activities, maintain audit continuity, and determine effectiveness.

a. Record activities on the checklists or notebooks.

6. Conduct the audit using the following methods or a combination of the following methods, and provide results to the ATL for inclusion into the audit report:

a. Examine objective evidence for proper and effective implementation of the QA program.

b. Interview personnel.

Audit Team

c. Review process objectives and measurement criteria.

d. Review records.

e. Observe activities, personnel performances, in-process analyses, and testing.

f. Determine the technical adequacy and effectiveness of analytical processes used in engineering, scientific, or operational aspects of quality affecting technical activities or processes.

7. Inform the ATL of audit progress, potential notable practices, problems observed, and deviations from requirements.

8. Record conditions adverse to quality on Form 16.02-1, "DR/CAR" in accordance with QAS 16.02.

9. For conditions CDA, verify that the condition is isolated and that the remedial actions taken by the responsible organization to correct conditions adverse to quality during the audit are completed before concluding audit fieldwork. Document the condition as CDA in accordance with QAS 16.02.

10. Record conditions, other than conditions adverse to quality, as *concerns* (see glossary).

ATL/Team Members

11. Immediately report conditions requiring prompt corrective action to management of the audited organization. For significant conditions adverse to quality that meet criteria for a stop work order under QAS 16.04, immediately notify the QAPM.

12. Upon discovering an imminent danger condition, report it immediately to affected personnel and the responsible supervisor/manager. Follow up in writing.

ATL

13. Elevate issues that cannot be resolved between the audit team and the audited organization to the QAPM for resolution.

14. Survey the observers during regular team meetings. Discuss observer inquiries to ensure applicability to audit scope.

a. If observer inquiries are not resolved with the observer, encourage the observer to document inquiries on Form 18.02-1/18.03-1, "Observer Inquiry."

b. Evaluate documented inquiries and respond on the Observer Inquiry form.

ATL

c. If an inquiry identifies a deviation from requirements during the audit, document the inquiry as a DR/CAR in accordance with QAS 16.02 and note this action on the Observer Inquiry form.

d. Sign the Observer Inquiry form, and provide a copy of the completed form to the observer.

e. Elevate unresolved inquiries to the NSNFP QAPM for resolution.

QAPM

15. Resolve issues that cannot be resolved between the audit team and the audit observers.

16. Document observer inquiry resolution and response on Form 18.02-1/ 18.03-1, sign the form, and provide a copy to the observer and ATL.

ATL

17. Conduct the post audit conference with the audit team and management of the audited organization to summarize the audit results. This meeting must include:

a. Notable practice(s), if any

b. An explanation of each individual deviation from requirements, if any

c. An effectiveness statement of each element audited

d. An explanation of the follow-up requirements of QAS 16.02 for DR/CARs

e. An explanation of how and when to provide responses to DR/CARs.

E. Completing the Audit Report

ATL

1. Prepare the formal audit report using input from audit team members; include the following information:

a. Signature page for the ATL and QAPM.

b. Executive summary that addresses the following information:

(1) Identification of organizations evaluated

(2) Dates audit was performed

(3) Base requirement (i.e., DOE/RW-0333P; NQA-1)

(4) A summarized description of conditions adverse to quality stating significance in the context of program impact

(5) State the number of CDAs, concerns, and notable practices.

ATL

c. Table of contents.

d. Statement on the effectiveness of the QA elements that were audited. Clearly state whether the implementation of the QA programs elements were effective or not effective. If implementation varied for activities audited, clearly state where implementation was effective and not effective.

e. Purpose and scope of the audit. This section should reflect criteria listed in the audit plan with a summary stating whether all criteria of the audit plan were addressed. Clearly identify any criteria or activity listed in the audit plan that could not be audited.

f. Quality Assurance Program discussion, including a description of each criterion or activity audited under the QA program. Include a description of each DR, CAR, conditions CDA, and notable practices. DRs and CARs are documented and controlled in accordance with QAS 16.02.

g. The identity of audit team members, observers, personnel that attended the preaudit conference and postaudit conference, and individuals contacted during the audit.

h. The identity of documents reviewed (include revision or date).

2. Attach a copy of the approved DR/CAR forms to the audit report. DRs and CARs are controlled in accordance with QAS 16.02 and are typically distributed for action 11 working days after the postaudit conference, separate from the audit report.

3. Sign the audit report and prepare an audit report transmittal letter or memo.

4. Submit the audit report transmittal letter and audit report to the NSNFP QAPM no later than 30 calendar days after completing the audit.

F. Report Distribution

QAPM

1. Approve the audit report, and issue it with the audit report transmittal letter (issuing the audit report represents audit closure even though DR/CARs may still be open) to the following:

a. Management of the audited organization

b. Manager, NSNFP

c. ATL and audit team members

d. Audit observers.

IV. REFERENCES

DOE/SNF/MTX-001, The National Spent Nuclear Fuel Program QARD Requirements Matrix, current revision

V. DEFINITIONS

Terms appearing in italics followed by the notation "see glossary" are defined in the NSNFP Documents Manual Introduction and Glossary.

VI. ATTACHMENTS

Attachment A, Audit Plan Content and Example Format

VII. RECORDS

The following records generated as a result of this procedure require retention in accordance with the identified classification and PMP 17.01.

Lifetime

A. Audit Notification Correspondence

B. Audit Plan

C. Completed Observer Inquiry Forms

D. Audit Transmittal Letter and Audit Report

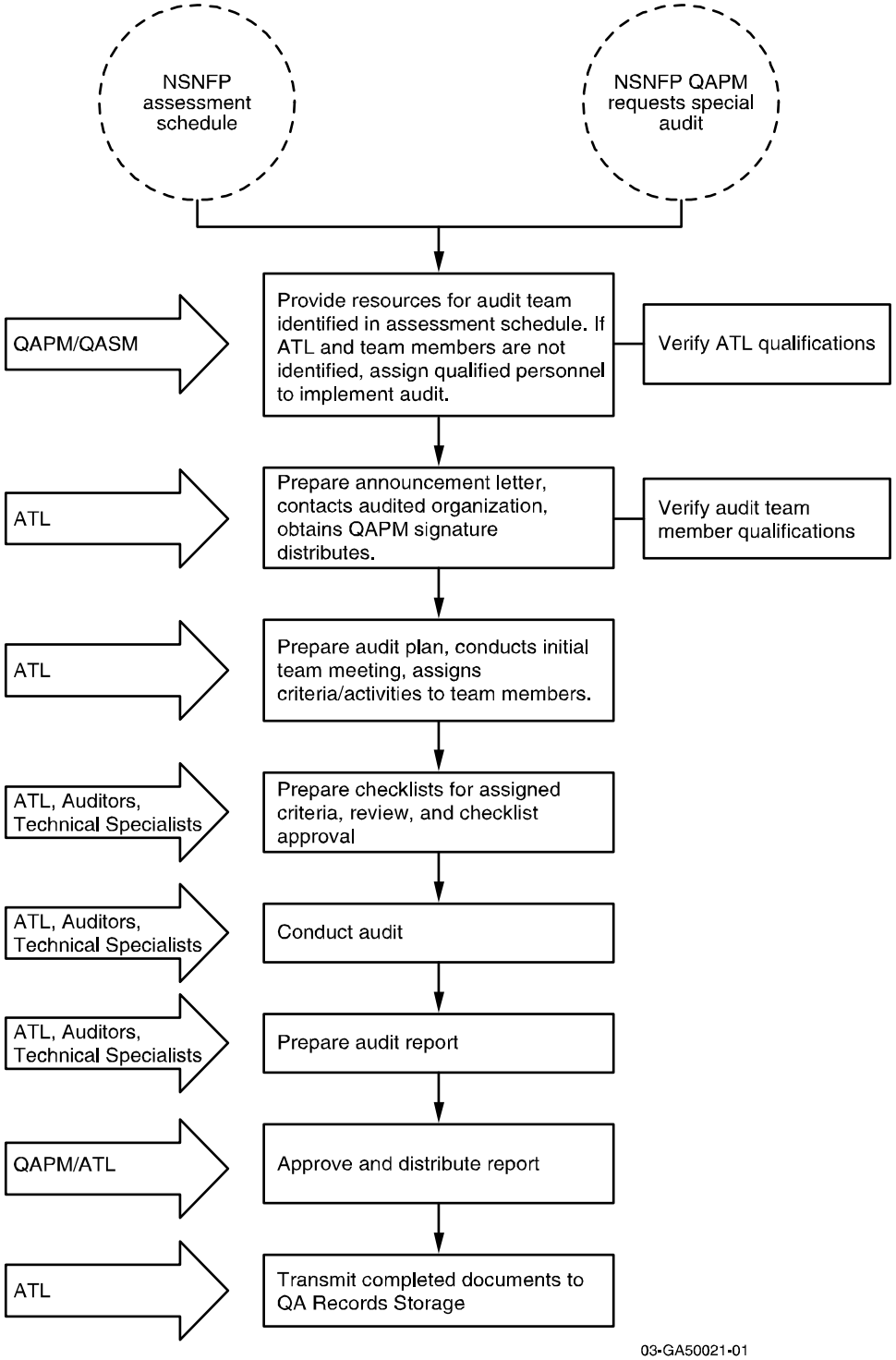
E. Observer Report, when applicable

F. Assessment Team Member Records (NSNFP Form 18.04-6)

Nonpermanent

A. Approved checklist.

VIII. PROCEDURE FLOW DIAGRAM



Attachment A

Audit Plan Content and Example Format

1. Audit Number: Enter the audit number.

2. Audit Title: Enter the title of the audit to be performed.

3. Auditing Organization: Enter the name of the organization that will perform the audit.

4. Audited Organization: Enter the name of the organization to be audited.

5. Scheduled Dates: Enter the scheduled date for performance of the audit.

6. Audit Team Members:

Identify audit team members by participation, i.e., ATL, auditors, technical specialists, observers.

7. Audit Scope:

Describe the audit scope.

8. Activities to be Audited:

Describe activities to be audited, for example: quality program elements, supplements, any special activities, processes, facilities or activities.

9. Applicable Requirements/Criteria:

List applicable source requirements documents and requirements matrix, including revision level.

10. Any Special or Technical Items to be Verified:

List any special or technical items to be verified.

11. Verification/Approval:

ATL: Print name, sign, and date to signify audit team members meet all the requirements.

QAPM: Print name, sign, and date to indicate approval and to acknowledge that the ATL is qualified and certified in accordance with PMP 18.04 and is independent of auditing activities.

ATL: _____ _____ _____
Printed Name Signature Date

QAPM: _____ _____ _____
Printed Name Signature Date